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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,175	07/01/1999	JAMES M. HOGLE	HU98-02PA	3518
21005	7590	05/13/2002	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			ZEMAN, ROBERT	
		ART UNIT	PAPER NUMBER	
		1645	U	
		DATE MAILED: 05/13/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/347,175	HOGLE ET AL.
	Examiner Robert A Zeman	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 4-58 is/are pending in the application.
- 4a) Of the above claim(s) 7-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2 and 4-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 2-8-2002 is acknowledged. Claims 1, 2, and 5-6 have been amended. Claim 3 has been canceled. Claim 58 has been added. Claims 1-2 and 4-58 are pending. Claims 7-57 have been withdrawn from consideration for being drawn to non-elected inventions. Claims 1-2, 4-6 and 58 are currently under examination.

This application contains claims 4-57 drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Election/Restrictions

With regard to Applicant's continued traversal of the restriction requirement outlined in Paper No. 15, said restriction was made final in the previous Office Action. Additionally, it should be noted that claims 41-45 are drawn to enhancing binding interactions which is not a biotechnological process under 35 U.S.C. 103(b) and the molecule of claim 1 is not required to be made by a biotechnological process as evidenced by claim 5. However, if Applicant submits, in writing, an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required. *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978). If Applicant does not desire to make such an admission, he is free to petition the Group director.

§ 1.144 Petition from requirement for restriction.

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Commissioner to review the requirement.

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Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested

Claim Objections Withdrawn

The objection to claims 1, 5 and 6 for the improper use of abbreviations is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 2 for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a ligand interaction peptide” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a chemical” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “an effector” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a signal amplification peptide” is withdrawn in light of the amendment thereto.

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The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “an enhancer recognition protein” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a small organic molecule” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a test substance” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a cytotoxic agent” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a substrate” is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “a solid substrate” is withdrawn in light of the amendment thereto.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “binding partners” is withdrawn. Cancellation of said claim has rendered the rejection moot.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2, 4-6 and 58 under 35 U.S.C. 102(b) as being anticipated by Chang et al. (Journal of Virology, Vol. 66 No. 10, Oct 1992, pages 6019-6027—IDS-5) is maintained for reasons the reasons outlined in the previous Office action in the rejection of claims 1-6. Cancellation of claim 3 has rendered the rejection of that claim moot.

Applicant argues:

1. The amended claims are not anticipated by the cited reference since the cited reference teaches fusion proteins of the full length HDAg.

Applicant's arguments have been fully considered and deemed non-persuasive. The rejected claims have been amended to recite the limitation "a peptide consisting essentially of amino acids 12 to 88...". Since it is unclear how the "consisting essentially of" language is being applied to an amino acid sequence, said term is being interpreted in the same manner as "comprising". Therefore the instant invention is still anticipated by the cited reference.

The rejection claims 1-2, 4-6 and 58 under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Virology, Vol. 169, Feb 1994, pages 169-175) is maintained for reasons the reasons outlined in the previous Office action in the rejection of claims 1-6. Cancellation of claim 3 has rendered the rejection of that claim moot.

Applicant argues:

1. The amended claims are not anticipated by the cited reference since the cited reference teaches fusion proteins of the full length HDAg.

Applicant's arguments have been fully considered and deemed non-persuasive. The rejected claims have been amended to recite the limitation "a peptide consisting essentially of amino acids 12 to 88...". Since it is unclear how the "consisting essentially of" language is being applied to an amino acid sequence, said term is being interpreted in the same manner as "comprising". Therefore the instant invention is still anticipated by the cited reference.

The rejection of claims 1-2, 4-6 and 58 under 35 U.S.C. 102(b) as being anticipated by Bonelli et al. (EP 0485347) is maintained for the reasons outlined in the previous Office action in the rejection of claims 1-6. Cancellation of claim 3 has rendered the rejection of that claim moot.

Applicant argues:

1. The amended claims are not anticipated by the cited reference since the cited reference teaches fusion proteins of the full length HDAg.

Applicant's arguments have been fully considered and deemed non-persuasive. The rejected claims have been amended to recite the limitation "a peptide consisting essentially of amino acids 12 to 88...". Since it is unclear how the "consisting essentially of" language is being applied to an amino acid sequence, said term is being interpreted in the same manner as "comprising". Therefore the instant invention is still anticipated by the cited reference.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-6 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase “consisting essentially of amino acids 12-88...”. Since it is unclear how the “consisting essentially of” language is being applied to an amino acid sequence the metes and bounds of the claimed invention cannot be determined.

Claim 58 is rendered vague and indefinite by the use of the term “blood factors”. It is unclear what is meant by said term. Is said term referring to blood components or merely factors that are blood-borne? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 58 is rendered vague and indefinite by the use of the term “negative selection factors”. It is unclear what is meant by said term. Negative selection for what? Under what conditions? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 58 is rendered vague and indefinite by the use of the term “anti-angiogenic factors”. It is unclear what is meant by said term. Under what conditions is said factor anti-angiogenic? In what animal? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 58 is rendered vague and indefinite by the use of the term “adrenergic receptors”. It is unclear what is meant by said term. Is said term referring to receptors that bind epinephrine or epinephrine-like compounds or is it referring to receptors that have epinephrine-like physiological effects. If Applicant is claiming the latter, what ligands activate said receptors? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the primary examiner, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN
PRM: DAW/MNF

Robert A. Zeman
May 13, 2002